C1

(c) presenting the at least one antigen or epitope thereof on a cell surface of the Langerhans cell to a lymphocyte, thereby inducing the immune response in the organism.

22. (3 x Amended) The method of claim 1, wherein at least one adjuvant is pertussis toxin or a derivative thereof having adjuvant activity.

23. (3 x Amended) The method of claim 1, wherein at least one adjuvant is cholera toxin (CT) or a derivative thereof having adjuvant activity.

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24. (3 x Amended) The method of claim 1, wherein at least one adjuvant is *E. coli* heat-labile enterotoxin (LT) or a derivative thereof having adjuvant activity.

25. (3 x Amended) The method of claim 1, wherein at least one adjuvant is diphtheria toxin (DT) or a derivative thereof having adjuvant activity.

26. (2 x Amended) The method of claim 1, wherein at least one adjuvant is *Pseudomonas* exotoxin A or a derivative thereof having adjuvant activity.

D4

31. (2 x Amended) A method of inducing an immune response comprising:

(a) applying a formulation to intact skin of an organism, wherein the formulation comprises (i) at least one antigen which is derived from a pathogen and (ii) at least one adjuvant, and at least some antigen which is not encapsulated induces the immune response; and

C3

(b) inducing the immune response in the organism without perforating the skin, wherein the immune response is specific for the antigen.

32. (3 x Amended) A method of inducing an immune response comprising:

(a) applying a formulation to intact skin of an organism, wherein the formulation comprises (i) at least one antigen which is derived from a pathogen and (ii)

at least one adjuvant, and at least some antigen which is not encapsulated induces the immune response;

(b) activating an antigen presenting cell with the at least one adjuvant; and

(c) presenting the at least one antigen or epitope thereof on a cell surface of the antigen presenting cell to a lymphocyte, thereby inducing the immune response in the organism.

C3

33. (2 x Amended) A method of inducing an immune response comprising:

(a) applying epicutaneously on an organism an effective amount of at least one antigen derived from a pathogen and which is not encapsulated,

(b) activating a Langerhans cell underlying the organism's skin with at least one adjuvant,

(c) signaling the Langerhans cell to migrate to a lymph node of the organism and mature into a dendritic cell therein, and

(d) presenting the at least one antigen or epitope thereof on a cell surface of the dendritic cell to a lymphocyte; thereby inducing the immune response in the organism, wherein the immune response is specific for the at least one antigen.

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50 ~~41~~. (Amended) The method of claim 31, wherein the formulation comprises an ADP-ribosylating exotoxin derivative which is less toxic but remains immunogenic.

51 ~~42~~. (Amended) The method of claim 31, wherein the formulation comprises a genetically produced derivative of ADP-ribosylating exotoxin in which ADP-ribosyl transferase activity is inactivated.

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52 ~~43~~. (Amended) The method of claim 31, wherein the formulation comprises a chemically produced derivative of ADP-ribosylating exotoxin in which ADP-ribosyl transferase activity is inactivated.

53 ~~44~~. (Amended) The method of claim 31, wherein the formulation comprises an ADP-ribosylating exotoxin B subunit.

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54 ~~45~~. (Amended) The method of claim 1, wherein the formulation is comprised of at least partially purified antigen molecules as chemical or recombinant conjugates.

55 ~~46~~. (Amended) The method of claim 1, wherein the formulation is comprised of an at least partially purified molecule containing both antigen and adjuvant properties.

56 ~~47~~. (Amended) The method of claim 1, wherein the formulation is comprised of at least some antigen molecules which are at least partially purified and lack adjuvant properties.

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57 ~~48~~. (Amended) The method of claim 1, wherein the antigen is at least partially purified and has a molecular weight greater than 800 daltons.

58 ~~49~~. (Amended) The method of claim 1, wherein the antigen is at least partially purified and has a molecular weight greater than 1000 daltons.

59 ~~50~~. (Amended) The method of claim 1, wherein the antigen is an at least partially purified polypeptide of greater than 800 daltons molecular weight.

60 ~~51~~. (Amended) The method of claim 1, wherein the antigen is an at least partially purified polypeptide of greater than 1000 daltons molecular weight.

62 ~~53~~. (Amended) A method of immunization comprising applying a formulation without lipid vesicles to intact skin of an organism, wherein the formulation is comprised of an effective amount of one or more at least partially purified ADP-ribosylating exotoxins or derivatives thereof having adjuvant activity.

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78 ~~69~~. (Amended) A method of immunization comprising hydrating intact skin of an organism; applying an effective amount of one or more adjuvants to the hydrated, intact skin; and separately administering one or more at least partially purified antigens which

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C-6 are derived from one or more pathogens in the absence of lipid vesicles such that the organism is effectively immunized.

Kindly enter the following new claims.

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79 ~~70~~. (New) The method of claim 1, wherein at least one adjuvant is an ADP-ribosylating exotoxin or derivative thereof having adjuvant activity.

80 ~~71~~. (New) The method of claim 1, wherein at least one adjuvant is a cytokine or a chemokine.

81 ~~72~~. (New) The method of claim 1, wherein at least one adjuvant is DNA from bacteria or containing unmethylated CpG motifs.

2nd DA

82 ~~73~~. (New) The method of claim 1, wherein at least one adjuvant binds a receptor on antigen presenting cells.

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83 ~~74~~. (New) The method of claim 73, wherein the receptor is GM_1-ganglioside.

84 ~~75~~. (New) The method of claim 73, wherein the receptor is α_2-macroglobulin receptor-low density lipoprotein receptor-related protein.

85 ~~76~~. (New) The method of claim 31, wherein at least one adjuvant is pertussis toxin or a derivative thereof having adjuvant activity.

86 ~~77~~. (New) The method of claim 31, wherein at least one adjuvant is cholera toxin (CT) or a derivative thereof having adjuvant activity.

87 ~~78~~. (New) The method of claim 31, wherein at least one adjuvant is *E. coli* heat-labile enterotoxin (LT) or a derivative thereof having adjuvant activity.

88 78. (New) The method of claim 31, wherein at least one adjuvant is diphtheria toxin (DT) or a derivative thereof having adjuvant activity.

89 80. (New) The method of claim 31, wherein at least one adjuvant is *Pseudomonas* exotoxin A or a derivative thereof having adjuvant activity.

90 81. (New) The method of claim 31, wherein at least one adjuvant is an ADP-ribosylating exotoxin or derivative thereof having adjuvant activity.

91 82. (New) The method of claim 31, wherein at least one adjuvant is a cytokine or a chemokine.

92 83. (New) The method of claim 31, wherein at least one adjuvant is DNA from bacteria or containing unmethylated CpG motifs.

93 84. (New) The method of claim 31, wherein at least one adjuvant binds a receptor on antigen presenting cells.

94 85. (New) The method of claim 84, wherein the receptor is GM_1-ganglioside.

95 86. (New) The method of claim 84, wherein the receptor is α_2-macroglobulin receptor-low density lipoprotein receptor-related protein.

96 87. (New) The method of claim 31, wherein the formulation is comprised of at least partially purified antigen molecules as chemical or recombinant conjugates.

97 88. (New) The method of claim 31, wherein the formulation is comprised of an at least partially purified molecule containing both antigen and adjuvant properties.

98 ~~89~~. (New) The method of claim 31, wherein the formulation is comprised of at least some antigen molecules which are at least partially purified and lack adjuvant properties.

99 ~~90~~. (New) The method of claim 31, wherein the antigen is at least partially purified and has a molecular weight greater than 800 daltons.

100 ~~91~~. (New) The method of claim 31, wherein the antigen is at least partially purified and has a molecular weight greater than 1000 daltons.

101 ~~92~~. (New) The method of claim 31, wherein the antigen is an at least partially purified polypeptide of greater than 800 daltons molecular weight.

102 ~~93~~. (New) The method of claim 31, wherein the antigen is an at least partially purified polypeptide of greater than 1000 daltons molecular weight.

103 ~~94~~. (New) The method of claim 1 further comprising hydrating the intact skin and applying the formulation with an occlusive dressing.

104 ~~95~~. (New) The method of claim 30 further comprising hydrating the intact skin before application of the formulation and applying the formulation with an occlusive dressing.

105 ~~96~~. (New) The method of claim 31 further comprising hydrating the intact skin before application of the formulation and applying the formulation with an occlusive dressing.

106 ~~97~~. (New) The method of claim 32 further comprising hydrating the intact skin before application of the formulation and applying the formulation with an occlusive dressing.

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167 ~~98~~. (New) The method of claim 53 further comprising hydrating the intact skin before application of the formulation and applying the formulation with an occlusive dressing.

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